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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|---|---|---|---|
| 10/026,288 | 12/19/2001 | Jayarama K. Shetty | GC712 | 8114 |

7590 04/29/2004

Genencor International, Inc.
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| EXAMINER | |
|---|---|
| PRATS, FRANCISCO CHANDLER | |
| **ART UNIT** | **PAPER NUMBER** |
| 1651 | |

DATE MAILED: 04/29/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/026,288 | SHETTY ET AL. | |
| | Examiner | Art Unit | |
| | Francisco C Prats | 1651 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *15 March 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *3-10 and 12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3-10 and 12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

**DETAILED ACTION**

The amendment filed March 15, 2004, has been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claims 3-10 and 12 are pending and are examined on the merits.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3-10 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shetty et al ("Factors Affecting the

Economics of Glucose Production," Delivering Innovation Through Biotechnology, Genencor International, Inc., (1998)) in view of JP 10-136979.

Shetty discloses a process of preparing glucose from starch, said process using the claimed process parameters. See, e.g. pages 6 and 14. Shetty differs from the claims in that Shetty uses a different α-amylase enzyme than that recited in the claims. However, Shetty discloses that α-amylases active at acidic pH are advantageous in processes of producing glucose from starch. Specifically, the liquefaction step is improved by decreasing chemical demand for pH adjustment, reducing color and by-product formation, and lowering refining requirements and costs (Shetty, page 7). Also, the lower pH afforded by the use of acidophilic α-amylase eliminates the undesirable formation of maltulose (Shetty, page 8). Shetty also discloses that enzymes which do not require calcium or stability are advantageous, as are relatively thermostable enzymes. Shetty, page 11, last sentence. ("It is evident from the above data that an improved thermostable alpha-amylase which can operate at a pH below 6.0 and at lower or no calcium will significantly reduce refining costs and improve the final glucose yield.")

As is evident from the English abstract, JP '979 discloses an α-amylase which meets exactly the criteria disclosed by

Shetty as being desirable and advantageous for use in the disclosed process of preparing glucose from starch. Specifically, the enzyme is thermostable, acid-stable, optimally active at a pH of about 4, and does not require calcium for activity (see Table 2). Thus, the artisan of ordinary skill practicing Shetty's process clearly would have recognized that the enzyme disclosed by JP '979 possesses all the properties required for use in Shetty's process. The artisan of ordinary skill would therefore clearly have been motivated to have used the enzyme of JP '979 in Shetty's process. A holding of obviousness is therefore required.

It is noted that the claims have been amended to require the DE of about 10-12 to be reached within 60-90 minutes of adding the amylase. However, it is respectfully submitted that the new claim language does not serve to distinguish the claims from the cited prior art. Specifically, it is noted that at 90 minutes the DE of the various liquefaction processes disclosed by Shetty is about 10, which is encompassed by the lower limit of the presently claimed DE range of "about 10-12." See page 14 of Shetty, especially figs. 2 and 3. Thus, viewing the cited prior art, it is respectfully submitted that the artisan of ordinary skill had a reasonable expectation that the claimed DE could be reached in the claimed amount of time by following the

teachings of Shetty. A holding of obviousness is therefore required.

***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 3-10 and 12 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-52 of copending Application No. 10/026,753 in view of Shetty et al ("Factors Affecting the Economics of Glucose Production," Delivering Innovation Through Biotechnology, Genencor International, Inc., (1998)).

The claims under examination differ from the claims of the '753 application only to the extent that the instant claims recite an additional saccharification step not recited in the

claims of the '753 application. However, as is clear from the disclosure in Shetty, the hydrolysis of enzyme-liquefied starch to produce glucose is well known in the art. Thus, the presently claimed addition of saccharification steps to the liquefaction process recited in the claims of the '753 application must be considered an obvious variation of the subject matter recited in the claims of the '753 application. Lastly, it is again noted that the claims have been amended to require the DE of about 10-12 to be reached within 60-90 minutes of adding the amylase. However, it is respectfully submitted that the new claim language does not serve to distinguish the claims from the cited prior art. Specifically, it is noted that at 90 minutes the DE of the various liquefaction processes disclosed by Shetty is about 10, which is encompassed by the lower limit of the presently claimed DE range of "about 10-12." See page 14 of Shetty, especially figs. 2 and 3. Thus, viewing the cited prior art, it is respectfully submitted that the artisan of ordinary skill had a reasonable expectation that the claimed DE could be reached in the claimed amount of time by following the teachings of Shetty. A holding of obviousness is therefore required.

This is a provisional obviousness-type double patenting rejection.

***Response to Arguments***

All of applicant's argument has been fully considered, but is not persuasive of error. It is noted that the Shetty reference discloses the advantages of the enzyme disclosed therein. However, that disclosure does not require the artisan of ordinary skill to ignore other pieces of relevant prior art, as urged by applicant. Rather, the artisan of ordinary skill is legally considered to have knowledge of all relevant prior art. Moreover, prior art must be considered as a whole. Thus, the artisan of ordinary skill, viewing the Shetty reference as a whole, clearly would have recognized that α-amylase enzymes which are thermostable, acid-stable, optimally active at a pH of about 4, and do not require calcium for activity, were particularly desirable in processes of making glucose from starch by enzymatic hydrolysis. The artisan of ordinary skill, being aware of the disclosure of JP '979, clearly would also have recognized that the α-amylase disclosed therein precisely met the criteria for advantageous enzymes set out by Shetty. The artisan of ordinary skill would therefore have been

motivated by the disclosures of Shetty and JP '979 to have used the JP '979 amylase in the Shetty process.

It is also noted that the enzyme of JP '979 is disclosed as being stable at pH values of 4.5 to 5.0. However, this is not a teaching away, as applicant appears to assert. Applicant's argument ignores the fact that the claims only require the claimed process to be conducted at pH levels "as low as 3.0" Thus, the claims encompass conducting the starch hydrolysis process at values well within the optimal pH of 4.0 disclosed by JP '979. Moreover, new claim 12 even recites a pH range "between about 4.0 and 4.5," which is exactly the optimal pH range of the α-amylase disclosed by JP '979. Thus, rather than a teaching away, on the current record the claims recite a process clearly suggested by the physical properties of the enzyme disclosed in the prior art.

It is yet again noted that the claims have been amended to require the DE of about 10-12 to be reached within 60-90 minutes of adding the amylase. However, it is respectfully submitted that the new claim language does not serve to distinguish the claims from the cited prior art. Specifically, it is noted that at 90 minutes the DE of the various liquefaction processes disclosed by Shetty is about 10, which is encompassed by the lower limit of the presently claimed DE range of "about 10-12."

See page 14 of Shetty, especially figs. 2 and 3. Thus, viewing the cited prior art, it is respectfully submitted that the artisan of ordinary skill had a reasonable expectation that the claimed DE could be reached in the claimed amount of time by following the teachings of Shetty. As an aside, applicant is reminded that the claims in this application have been amended to require the claim-recited DE of 10-12 to be reached within 60-90 minutes, a value clearly achieved in the prior art.

Lastly, with respect to the issue of obviousness-type double patenting, applicant's attention is directed to MPEP § 804.02, subsection VI, which requires terminal disclaimers to be filed, even in applications having enforceable terms lasting 20 years from filing. The rationale provided therein is twofold. First, in view of the policy of granting patent term extensions, applications having a common parentage would not necessarily have the same patent term. Second, the terminal disclaimer links together the ownership of the patent rights granted, so as "to avoid the potential for harassment of an accused infringer by multiple parties with patents covering the same patentable invention." MPEP § 804.02. The provisional rejection must therefore be maintained.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C Prats whose telephone number is 571-272-0921. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can

be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Francisco C Prats
Primary Examiner
Art Unit 1651

FCP